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10/728,496	12/05/2003	Punam K. Saha	P-2944	9711

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EXAMINER

KRASNIC, BERNARD

ART UNIT	PAPER NUMBER
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2624

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/728,496

Applicant(s)

SAHA ET AL.

Examiner

Bernard Krasnic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2-22-2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because the abstract used the phrase "The invention deals" in line 4. It is suggested to be -- The method deals --.

Correction is required. See MPEP § 608.01(b).

Claim Objections

3. Claims 1, 5, 10, 14, 17, 21-22, 24, and 29-30 are objected to because of the following informalities:

Claim 1, line 4, claim 17, lines 4-5, claim 29, line 7, claim 30, line 8 respectively:

"calculating the fuzzy" should be -- calculating a fuzzy --.

Claims 5 and 21, line 1 respectively: "the step of sampling FDT values along the" should be -- a step of sampling FDT values along a --.

Claim 10, line 1: "sampled along the medial" should be -- sampled along a medial --.

Claim 14, line 1: "the targetted object" should be -- the targeted object --.

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Claim 22, line 2: The claim must end with a period -- . --.

Claim 24, lines 1-2 respectively: "monitoring the progression" should be -- monitoring a progression --.

Claim 29, line 4: "object from an image" should be -- object from the image --.

Claim 30, line 2: "::" should be -- : --.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. Claims 1-21 and 25-30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-21 and 25-30 are drawn to a computer implemented process that merely manipulates data or an abstract idea, or merely solves a mathematical problem without a limitation to a practical application in the technological arts. Claims 1-21 and 25-30 are essentially calculating fuzzy distance transform (FDT) which is basically a mere manipulation of data or a mere solution to a mathematical problem with no practical application, whereas claims 22-24 are using the results of the computer implemented FDT process to further select and administer a therapy which definitely is a limitation toward a practical application.

In order for a claimed invention to accomplish a practical application, it must produce a "useful, concrete and tangible result" *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601-02 (see MPEP 2106.II.A). A practical application can be achieved through recitation of "a physical transformation outside the computer for which a

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practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan", or "limited to a practical application within the technological arts" (MPEP 2106 IVB2(b)). Currently, claims 1-21 and 25-30 meets neither of these criteria. In order to for the claimed process to produce a "useful, concrete and tangible" result, recitation of one or more of the following elements is suggested:

- 1 The manipulation of data that represents a physical object or activity transformed from outside the computer (MPEP 2106 IVB2(b)(i)).
- 2 A recitation of a physical transformations outside the computer, for example in the form of pre or post computer processing activity (MPEP 2106 IVB2(b)(i)).
- 3 A direct recitation of a practical application in the technological arts (MPEP 2106 IVB2(b)(ii)).

5. Further, claims 25-28 and 30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 25-28 and 30 are drawn to functional descriptive material NOT claimed as residing on a computer readable medium. MPEP 2106.IV.B.1(a) (Functional Descriptive Material) states:

"Data structures not claimed as embodied in a computer-readable medium are descriptive material per se and are not statutory because they are not capable of causing functional change in the computer."

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"Such claimed data structures do not define any structural or functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure's functionality to be realized."

Claims 25-28 and 30, while defining a "programming based algorithm" and a "computer-readable signal-bearing medium", does not define a "computer-readable medium" and is thus non-statutory for that reasons. A "programming based algorithm" and a "computer-readable signal-bearing medium" can range from paper on which the program is written, to a program simply contemplated and memorized by a person. The examiner suggests amending the claim to embody the program on "computer-readable medium" in order to make the claim statutory. "A dynamic programming-based algorithm to compute" in claim 25 line 1 should be -- A computer readable medium encoded with computer readable instructions for computing --. "The algorithm of" in claims 26-28 line 1 should be -- The computer readable medium of --. "A device for analyzing digital images by a fuzzy distance transform based computational method comprising: a computer-readable signal-bearing medium;" should be -- A computer readable medium encoded with computer readable instructions for analyzing digital images by a fuzzy distance transform based computational method comprising: --.

"In contrast, a claimed computer-readable medium encoded with the data structure defines structural and functional interrelationships between the data structure and the computer software and hardware components which permit the data structure's functionality to be realized, and is thus statutory."

- MPEP 2106.IV.B.1(a)

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Re Claim 11: The limitation "FDT is in digital cubic space" does not further limit its preceding claim. In particular, it does not further limit preceding claim 4 under which claim 11 is dependent upon, therefore rendering claim 11 indefinite.

Claims 12-15 are dependent upon claim 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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9. Claims 1-21 and 25-30 are rejected under 35 U.S.C. 102(a) as being anticipated by Gomberg ("Fuzzy distance transform: Theory, algorithms, and applications" – Computer Vision and Image Understanding – June 2002, vol. 86, pages 171-190).

Re Claim 1: Gomberg discloses a fuzzy distance transform-based computational method / FDT algorithms for analyzing digital images / medical images defining a volumetric region / 3D or cubic spaces of an object from an image / medical image comprising: (a) obtaining an image of the targeted object / digital object; (b) finding a plurality of points in the image to generate a fuzzy subset and calculating the fuzzy distance transform (FDT) of the fuzzy subset (see page 171-172, paragraph "This paper describes the theory and algorithms ...").

Re Claim 17: Gomberg discloses a fuzzy distance transform-based computational method / FDT algorithms for evaluating or diagnosing bone disease / fracture in a subject / human by analyzing digital images / medical images defining at least one volumetric region / 3D or cubic spaces of bone / trabecular bone from or in said subject, said method comprising: (a) obtaining an image of targeted bone region / digital image of trabecular bone; (b) finding a plurality of points in the image to generate a fuzzy subset and calculating the fuzzy distance transform (FDT) of the fuzzy subset (see page 171-172, paragraph "This paper describes the theory and algorithms ...", Fig. 7, pages 186-187, paragraph "The second example of thickness ..." and "A further demonstration of the effectiveness ...").

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Re Claim 25 [as best understood by the Examiner]: Gomberg discloses a dynamic programming-based algorithm to compute fuzzy distance transform (FDT) by means of a plurality of points in an image of a target object / digital image used to generate a fuzzy subset, and to calculate the FDT of the fuzzy subset, said FDT terminating in a finite number of steps (see page 171-172, paragraph "This paper describes the theory and algorithms ...").

The limitation "by means of" in line 2 of claim 25 invokes 35 U.S.C. 112, sixth paragraph.

As to claim 29, the claim is the corresponding means plus function system claim to claim 1 respectively. The discussions are addressed with regard to claim 1.

The limitations "means for obtaining" in line 3, "means for defining" in line 4, "means for finding" in line 5, and "means for calculating" in line 7 of claim 29 invoke 35 U.S.C. 112, sixth paragraph.

Re Claim 30 [as best understood by the Examiner]: Gomberg discloses a device for analyzing digital images by a fuzzy distance transform-based computational method / FDT algorithm comprising: a computer-readable signal-bearing medium; means in the medium for acquiring or reading a 3D image / medical image of at least one volumetric region / 3D or cubic space of a target object / digital object; means in the medium for identifying a plurality of points in the image to generate a fuzzy subset; and a means in the medium for calculating the fuzzy distance transform (FDT) of the fuzzy subset (see

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page 171-172, paragraph "This paper describes the theory and algorithms ...", the programmed algorithm is inherently presented for computing on a computer).

The limitations "means for acquiring" in line 4, "means for identifying" in line 6, and "means for calculating" in line 8 of claim 30 invoke 35 U.S.C. 112, sixth paragraph.

Re Claim 2: Gomberg further discloses the calculating step comprises assigning to a point in the fuzzy subset its respective fuzzy distance from a complement of a support of the fuzzy subset (page 171, paragraph "This paper describes the theory and algorithms ...", lines 16-17).

Re Claim 3: Gomberg further describes the support comprises a set of all points in the fuzzy subset with a value greater than or equal to a support value (page 171, paragraph "This paper describes the theory and algorithms ...", lines 11-13).

Re Claim 4: Gomberg further discloses the FDT is in digital cubic space (page 171, paragraph "This paper describes the theory and algorithms ...", line 18).

Re Claim 5: Gomberg further discloses the step of sampling FDT values along the medial axis of the support of the fuzzy subset to estimate regional target object / digital object thickness distribution (see page 182, Fig. 3 caption, page 187, Fig. 7 caption, page 184, Section – 4.1 Computation of Thickness).

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Re Claim 6: Gomberg further discloses the target object / digital object comprises bone marrow space, cortical bone, blood vessels or lung airways (see page 172, Section – INTRODUCTION, lines 14-16).

Re Claim 7: Gomberg further discloses the FDT is computed in digital cubic space of resolution of target object / digital object thickness or smaller (see page 172, Section – INTRODUCTION, line 9).

Re Claim 8: Gomberg further discloses the target object / digital object is in or from an animal or human subject / human trabecular bone (see Fig. 7).

Re Claim 9: Gomberg further discloses the image is obtained by magnetic resonance / MR or computed tomography / CT (see Figs. 6 and 7, page 186, paragraph “The second example of thickness ...”, paragraph “A further demonstration ...”).

Re Claim 10: Gomberg further discloses the FDT values are sampled along the medial axis directly computed from the fuzzy subset (see page 182, Fig. 3 caption, page 187, Fig. 7 caption, page 184, Section – 4.1 Computation of Thickness).

Re Claim 16: Gomberg further discloses applying one or more additional steps consisting of skeletonizing, feature extracting; analyzing morphological or shape-based

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object, computing regional object depth; calculating average or regional object thickness distribution; and local scaling (see page 172, Section – INTRODUCTION, lines 9-11).

As to claims 11-15, the discussions are addressed with respect to claims 4 and 6-9.

As to claims 18-21, the discussions are addressed with respect to claims 2-5.

As to claims 26-28, the discussions are addressed with respect to claims 2-4.

The limitation “means for assigning” in line 1 of claim 26 invokes 35 U.S.C 112, sixth paragraph.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gomberg (“Fuzzy distance transform: Theory, algorithms, and applications”) in view of Gomberg (“In vivo magnetic resonance based virtual bone biopsy” - Dissertation). The

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teachings of Gomberg ("Fuzzy distance transform: Theory, algorithms, and applications") have been discussed above.

However, Gomberg ("Fuzzy distance transform: Theory, algorithms, and applications") fails to disclose or fairly suggest selecting a therapy based on the diagnosis or evaluation.

Gomberg (Dissertation), as recited in claim 22, discloses selecting a therapy based on the diagnosis or evaluation of bone disease in the subject (see Chapter 1, pages 1-3, "indicate optimal treatment to restore bone strength and monitor therapy response").

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gomberg's ("Fuzzy distance transform: Theory, algorithms, and applications") evaluating and diagnosing the bone fracture method using Gomberg's (Dissertation) teachings by including the ability to select and administer therapy to the fracture while monitoring the progression or regression of the bone fracture in order to have a possible noninvasive structural analysis of trabecular bones (see Gomberg, Chapter 1, page 3, paragraph 2).

Re Claim 23: Gomberg (Dissertation) further discloses administering said therapy to said subject (see Chapter 1, pages 1-3, "indicate optimal treatment to restore bone strength and monitor therapy response").

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Re Claim 24: Gomberg (Dissertation) further discloses monitoring the progression or regression of bone disease in the subject, during or at one or more times after administering said selected therapy (see Chapter 1, pages 1-3, "indicate optimal treatment to restore bone strength and monitor therapy response").

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wehrli et al discloses a virtual bone biopsy; George et al discloses a medical imaging system for displaying, manipulating and analyzing three dimensional images; Gomberg discloses a novel theory and algorithm for fuzzy distance transform and its applications; Song discloses Integrated Processing System for In vivo MR images of trabecular bone networks.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Krasnic whose telephone number is (571) 270-1357. The examiner can normally be reached on Mon-Thur 9:00am-3:00pm and every other Friday 9:00am-3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jingge Wu can be reached on (571) 272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bernard Krasnic
April 6, 2007



JINGGE WU
SUPERVISORY PATENT EXAMINER